

REMARKS/ARGUMENTS

Claims 1, 3, 5-16, 18, and 20-28 remain in the application. Claims 1, 14, 16, and 28 have been amended. Claims 5 and 20 have been canceled. Claims 29 and 30 have been added. Reconsideration of this application, as amended, is respectfully requested.

Claims 1 and 16 have been amended to specify the following:

- (1) the biosensor is for determining the concentration of an analyte in a liquid sample;
- (2) the biosensor includes an optional layer comprising (i) at least one enzyme and (ii) at least one mediator overlying the working electrode;
- (3) in the presence of the analyte, electrons are transferred from the at least one enzyme to the at least one mediator to the working electrode.

Support for this amendment can be found at page 1, lines 7-9 (paragraph [0002]), at page 13, lines 3-5 (paragraph [0043]), and at page 6, lines 5-8 (paragraph [0020]) of the specification, and in claims 5 and 20, as originally filed. Claims 29 and 30 have been added to specify that the enzyme of claim 1 and the enzyme of claim 16 is a dehydrogenase. Support for these claims can be found at page 17, lines 4-12 of the specification and in claims 4 and 19, as originally filed.

Claims 14 and 28 have been amended to insert the term "space" between the words "capillary" and "is". Support for this amendment can be found at page 10, lines 4-14, at page 21, lines 18-21, and at page 22, lines 13-29.

Claims 1, 3, 5-16, 18, and 20-28 were rejected under 35 U. S. C. §103 (a) as being unpatentable over Feldman et al. and Gilmartin. This rejection is respectfully traversed for the following reasons.

Feldman et al., U. S. Patent No. 6,299,757 (hereinafter "Feldman et al."), was described on page 15 of the AMENDMENT AND RESPONSE filed December 13, 2004.

Gilmartin, U. S. Patent No. 5,795,453 (hereinafter "Gilmartin"), was described on pages 13-14 of the AMENDMENT AND RESPONSE UNDER 37 CFR 1.116 filed May 5, 2005.

The claims of the present application recite that (1) at least one enzyme or (2) at least one enzyme and at least one mediator be incorporated in at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode, or the electrical contact associated with the working electrode. According to the claims of the present application, the enzyme either need not be mixed with the mediator or can be mixed with the mediator to prepare the substance that is incorporated in at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode, or the electrical contact associated with the working electrode. An optional reagent layer (reference numeral 22 or 22') can be used to furnish any enzyme or mediator required to carry out the determination of the concentration of the analyte. TABLE 1 on page 12 of the specification discloses biosensors, i.e., Biosensor III and Biosensor IV, in which an enzyme need not be mixed with a mediator for use in the conductive track or the electrical contact of a biosensor. TABLE 1 on page 12 of the specification further discloses a biosensor, i.e., Biosensor V, in which an enzyme can be mixed with a mediator for use in the conductive track or the electrical contact of a biosensor. Feldman et al. does not disclose the use of an enzyme in a conductive track or in an electrical contact of a biosensor.

Gilmartin discloses the use of a hydrogen peroxide measurement system based on the classical Fenton-Haber process whereby peroxide chemically oxidizes Fe^{2+} ions (or other metals). The resulting trivalent species is electrochemically reduced by an appropriate potential thus closing the catalytic cycle. See column 4, lines 13-20 of Gilmartin. The following table lists locations of additional disclosures in Gilmartin where the use of a hydrogen peroxide measurement system is described:

Column	Lines
1	51-55
1	58-63
2	19-28
2	29-37
3	1-6
3	25-32
3	33-42
3	47-54
3	61-67
4	1-9
4	10-20
4	37-42
4	65-67
5	1-15
5	16-24
5	25-27
5	46-61
6	6-11
6	44-49
7	1-15
8	1-7
8	18-27
9	27-32
9	65-66
10	10-11
10	28-30
11	40-45
12	8-10
13	45-53
16	43-46
16	63-67
18	24-27
20	EXAMPLE 1
20	EXAMPLE 2
25	Claims 1-4
26	Claims 5-21

As shown in FIG. 2 of Gilmartin, electron transfer requires the use of the intermediate hydrogen peroxide. Thus, Gilmartin fails to disclose the use of an electrode arrangement wherein in the presence of the analyte, electrons are transferred from the at least one enzyme to the at least one mediator to the working electrode.

The interaction between the enzyme and the mediator recited in the claims of this application is significantly different from the interaction between the oxidase enzyme and the ferro isoindole ringed compound disclosed in Gilmartin because the latter interaction generates hydrogen peroxide, which reacts with the electron transfer agent. The interaction between the mediator and the enzyme recited in claims 1 and 16 does not generate hydrogen peroxide. As amended, claims 1 and 16 specify that in the presence of the analyte, electrons are transferred from the at least one enzyme to the at least one mediator to the working electrode. The formation of hydrogen peroxide is not a feature of claims 1 and 16 of this application. Accordingly, the combination of Feldman et al. and Gilmartin fails to render claims 1 and 16 obvious to one of ordinary skill in the art.

In effect, the rejection is based on a piecemeal reconstruction of the prior art, which is impermissible, because it is impermissible within the framework of 35 U. S. C. §103 to pick and choose from any one reference only so much of it as will support a given position (i.e., the conductive track in Gilmartin), to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art (i.e., the interaction between the oxidase enzyme and the ferro isoindole ringed compound disclosed in Gilmartin, which is not capable of transferring electrons from the at least one enzyme to the at least one mediator to the working electrode).

In view of the differences between the interaction between the oxidase enzyme and the ferro isoindole ringed compound in the conductive track described in Gilmartin and the interaction between the enzyme and the mediator recited in claims 1 and 16 of this application, as amended, and in the claims of this application depending from claims 1 (i.e., claims 3 and 5-16) and 16 (i.e., claims 18 and 20-28), it is submitted that the combination of

Feldman et al. and Gilmartin fails to render claims 1, 3, 5-16, 18, and 20-28 obvious to one of ordinary skill in the art.

Claims 1, 3, 10, 12, 13, and 15 were rejected under 35 U. S. C. §103 (a) as being unpatentable over Hughes in view of Gilmartin and Feldman et al. This rejection is respectfully traversed for the following reasons.

Hughes et al., U. S. Patent No. 6,129,823 (hereinafter "Hughes et al."), was described on page 15 of the AMENDMENT AND RESPONSE filed December 13, 2004.

Hughes et al. et al. does not disclose or suggest that at least one enzyme, or at least one enzyme and at least one mediator, is incorporated in at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode or the electrical contact associated with the working electrode. In Hughes et al., the reagents are deposited over the electrodes only.

The claims of the present application recite that (1) at least one enzyme or (2) at least one enzyme and at least one mediator be incorporated in at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode, or the electrical contact associated with the working electrode. According to the claims of the present application, the enzyme either need not be mixed with the mediator or can be mixed with the mediator to prepare the substance that is incorporated in at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode, or the electrical contact associated with the working electrode. An optional reagent layer (reference numeral 22 or 22') can be used to furnish any enzyme or mediator required to carry out the determination of the concentration of the analyte.

TABLE 1 on page 12 of the specification discloses biosensors, i.e., Biosensor III and Biosensor IV, in which an enzyme need not be mixed with a mediator for use in the conductive track or the electrical contact of a biosensor. TABLE 1 on page 12 of the specification further discloses a biosensor, i.e., Biosensor V, in which an enzyme can be mixed with a mediator for use in the conductive track or the electrical contact of a biosensor.

The deficiencies in the combination of Feldman et al. and Gilmartin are described in great detail on pages 8-10 of this AMENDMENT AND

RESPONSE. Hughes et al. fails to remedy these deficiencies, in particular, the deficiency arising from the formation of the hydrogen peroxide intermediate required by Gilmartin.

In effect, this rejection too is based on a piecemeal reconstruction of the prior art, which is impermissible, because it is impermissible within the framework of 35 U. S. C. §103 to pick and choose from any one reference only so much of it as will support a given position (i.e., the conductive track in Gilmartin), to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art (i.e., the interaction between the oxidase enzyme and the ferro isoindole ringed compound disclosed in Gilmartin, which is not capable of transferring electrons from the at least one enzyme to the at least one mediator to the working electrode).

In view of the differences between the interaction between the oxidase enzyme and the ferro isoindole ringed compound in the conductive track described in Gilmartin and the interaction between the enzyme and the mediator recited in claim 1 of this application, as amended, and in the claims of this application depending from claim 1 (i.e., claims 3, 10, 12, 13, and 15), it is submitted the combination of Hughes et al., Gilmartin, and Feldman et al. fails to render claims 1, 3, 10, 12, 13, and 15 obvious to one of ordinary skill in the art.

Claims 1, 3, 5, 8, and 10 stand rejected under 35 U. S. C. §103 (a) as being unpatentable over Gilmartin in view of Feldman et al. This rejection is respectfully traversed for the following reasons.

The deficiencies of the combination of Feldman et al. and Gilmartin were discussed on pages 8-10 of this AMENDMENT AND RESPONSE. These deficiencies are likewise applicable to this ground of rejection. In effect, the rejection is based on a piecemeal reconstruction of the prior art, which is impermissible, because it is impermissible within the framework of 35 U. S. C. §103 to pick and choose from any one reference only so much of it as will support a given position (i.e., the conductive track in Gilmartin), to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art (i.e., the interaction between the oxidase enzyme and the ferro isoindole ringed compound

disclosed in Gilmartin, which is not capable of transferring electrons from the at least one enzyme to the at least one mediator to the working electrode).

In view of the differences between the interaction between the oxidase enzyme and the ferro isoindole ringed compound in the conductive track described in Gilmartin and the interaction between the enzyme and the mediator recited in claim 1, as amended, and in the claims of this application depending from claim 1 (i.e., claims 3, 5, 8, and 10), it is submitted that the combination of Gilmartin and Feldman et al. fails to render claims 1, 3, 5, 8, and 10 obvious to one of ordinary skill in the art.

In view of the foregoing, it is submitted that claims 1, 3, 6-16, 18, and 21-28, as amended, and new claims 29 and 30 are in condition for allowance, and official Notice of Allowance is respectfully requested.

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